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Date: 9/26/01 Phone: 305-3910 Art Unit: 1616

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Please search for

Method of treating premenstrual dysphoric disorder (PMDD) by combination of gestagens and estrogens.

Elected species of gestagen is drospirenone and pro of estrogen is ethinylestradiol.

Pl. see attached sheets.

Thank you

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LI

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Norman NASHED

Application of Parent

Serial No.: 09/331,397

Filed: July 19, 2000

Examiner: NOT YET ASSIGNED

Group Art Unit: NOT YET ASSIGNED

For: **THERAPEUTIC GESTAGENS FOR THE TREATMENT OF PREMENSTRUAL
DYSPHORIC DISORDER**

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D. C. 20231

Sir:

Prior to examination, please amend the accompanying application as follows.

IN THE ABSTRACT:

Please delete the Abstract of the Disclosure in its entirety, and substitute therefor the Abstract which appears on a separate sheet attached hereto.

IN THE CLAIMS:

In the title, change "Claims" to --We claim:--

Please amend the claims as follows:

1. (Amended) [Use of a therapeutic gestagen for the production of a pharmaceutical agent for the treatment of] A method of treating premenstrual dysphoric disorder [(PMDD)], comprising administering to a patient in need of such treatment a therapeutically effective amount of gestagen.

2. (Amended) [Use of] The method of claim 1, wherein the gestagen is drospirenone, cyproterone acetate, or dienogest [according to claim 1].

3. (Amended) [Use according to] The method of claim 1, further comprising administering [together with] an estrogen.

4. (Amended) [Use according to] The method of claim 3, wherein the estrogen is [together with a]synthetic [estrogen].

5. (Amended) [Use according to] The method of claim 4, [together with] wherein the estrogen is ethinylestradiol.

6. (Amended) [Use according to] The method of claim 3, [together with] wherein the estrogen is an estrogen sulfamate.

7. (Amended) [Use according to] The method of claim 3, [together with a] wherein the estrogen is natural [estrogen].

8. (Amended) [Use according to] The method of claim 7, [together with] wherein the estrogen is estradiol, estradiol valerate or another estradiol ester.

9. (Amended) [Use according to] The method of claim 1, wherein the gestagen is administered only during the luteal phase of the female menstrual cycle.

10. (Amended) [Use according to] The method of claim 9, wherein the gestagen is administered from day 10 to 28 of the menstrual cycle.

11. (Amended) [Use of] The method of claim 1, wherein the gestagen is [according to claim 1] drospirenone, and it is administered in an amount of 0.5 mg to less than 5 mg daily.

12. (Amended) [Use of ethinylestradiol according to] The method of claim 5, wherein the ethinylestradiol is administered in an amount of 0.010 to 0.05 mg daily.

13. (Amended) [Use of estradiol according to] The method of claim 8, wherein estradiol is administered in an amount of 1.0 [g] to 3.0 mg daily.

Please add the following new claims:

- 14. The method of claim 2, wherein the gestagen is drospirenone.
15. The method of claim 3, wherein the gestagen and estrogen are administered together.
16. The method of claim 15, wherein the gestagen and estrogen are administered orally.
- A2 17. The method of claim 8, wherein the estrogen is estradiol.
18. The method of claim 11, wherein the daily dose of drospirenone is 1.0 to 4.0 mg.
19. The method of claim 4, wherein the estrogen is an estratrien-3-amidosulfonate.
20. The method of claim 4, wherein the estrogen is a 14a, 15a-methylene steriod from the estrane series.
21. The method of claim 3, wherein the gestagen and estrogen are administered continuously.
22. The method of claim 3, wherein the gestagen and estrogen are administered sequentially.
23. The method of claim 3, wherein the gestagen and estrogen are administered cyclically.--